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Saponins of *Chenopodium quinoa*

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Registration Decision for Saponins of *Chenopodium quinoa*

Health Canada's Pest Management Regulatory Agency (PMRA), under the authority of the *Pest Control Products Act* and Regulations, is granting full registration for the sale and use of Saponins of *Chenopodium quinoa* Technical and Heads Up Plant Protectant, containing the technical grade active ingredient saponins of *Chenopodium quinoa*, against rhizoctonia canker and black scurf on potato seed pieces.

An evaluation of available scientific information found that, under the approved conditions of use, the product has value and does not present an unacceptable risk to human health or the environment.

These products were first proposed for registration in the consultation document[1] Proposed Registration Decision PRD2010-20, Saponins of *Chenopodium quinoa*. This Registration Decision[2] describes this stage of the PMRA's regulatory process for saponins of *Chenopodium quinoa* and summarizes the Agency's decision and the reasons for it. This decision is consistent with the proposed registration decision stated in PRD2010-20.

For more details on the information presented in this Registration Decision, please refer to the Proposed Registration Decision PRD2010-20, Saponins of *Chenopodium quinoa* that contains a detailed evaluation of the information submitted in support of this registration.

What Does Health Canada Consider When Making a Registration Decision?

The key objective of the *Pest Control Products Act* is to prevent unacceptable risks to people and the environment from the use of pest control products. Health or environmental risk is considered acceptable[3] if there is reasonable certainty that no harm to human health, future generations or the environment will result from use or exposure to the product under its conditions of registration. The Act also requires that products have value[4] when used according to label directions. Conditions of registration may include special precautionary measures on the product label to further reduce risk.

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1 "Consultation statement" as required by subsection 28(2) of the *Pest Control Products Act*.

2 "Decision statement" as required by subsection 28(5) of the *Pest Control Products Act*.

3 "Acceptable risks" as defined by subsection 2(2) of *Pest Control Products Act*.

4 "Value" as defined by subsection 2(1) of *Pest Control Products Act*" ... the product's actual or potential contribution to pest management, taking into account its conditions or proposed conditions of registration, and includes the product's (*a*) efficacy; (*b*) effect on host organisms in connection with which it is intended to be used; and (*c*) health, safety and environmental benefits and social and economic impact".

To reach its decisions, the PMRA applies modern, rigorous risk-assessment methods and policies. These methods consider the unique characteristics of sensitive subpopulations in humans (for example, children) as well as organisms in the environment (for example, those most sensitive to environmental contaminants). These methods and policies also consider the nature of the effects observed and the uncertainties when predicting the impact of pesticides. For more information on how the PMRA regulates pesticides, the assessment process and risk-reduction programs, please visit the Pesticides and Pest Management portion of Health Canada's website at healthcanada.gc.ca/pmra.

What Is Saponins of *Chenopodium quinoa*?

Saponins of *Chenopodium quinoa* are the main active components in the extract from the bran of *Chenopodium quinoa* seeds. Saponins are substances produced naturally by many plant species that have a wide range of bioactive properties, including antimicrobial effects on various fungi and bacteria. It has also been proposed that saponins may induce systemic acquired resistance (SAR) in treated plants.

Health Considerations

Can Approved Uses of Saponins of *Chenopodium quinoa* Affect Human Health?

Saponins of *Chenopodium quinoa* is unlikely to affect your health when used according to label directions.

Potential exposure to saponins of *Chenopodium quinoa* may occur when handling and applying the product. When assessing health risks, two key factors are considered: the levels where no health effects occur and the levels to which people may be exposed. The dose levels used to assess risks are established to protect the most sensitive human population (for example, children and nursing mothers). Only uses for which the exposure is well below levels that cause no effects in animal testing are considered acceptable for registration.

The technical grade active ingredient, Saponins of *Chenopodium quinoa* Technical, is of slight acute toxicity by the inhalation route, low toxicity via the oral and dermal routes, and minimally irritating to the eyes and skin. Based on available information and a long history of human consumption of the food commodity quinoa (which invariably contains residues of saponins of *Chenopodium quinoa* at the time of consumption), exposure to the active ingredient is unlikely to result in any short-term toxicity, prenatal developmental toxicity, genotoxicity, or chronic toxicity.

Residues in Water and Food

Dietary risks from food and water are not of concern.

The amount of saponins of *Chenopodium quinoa* present as a residue after application of the end-use product will not be detectable due to the low application rate, use pattern, and rapid biotransformation of the active ingredient. Furthermore, exposure to the active ingredient currently occurs in the Canadian diet from the consumption of quinoa (washed seeds of *Chenopodium quinoa*) as food.

Occupational Risks From Handling Heads Up Plant Protectant

Occupational risks are not of concern when Heads Up Plant Protectant is used according to label directions, which include protective measures

Pesticide applicators handling and applying Heads Up Plant Protectant to seed potatoes can come into direct contact with saponins of *Chenopodium quinoa* on the skin and in the eyes, as well as by accidental ingestion and inhalation. The precautionary label statements adequately mitigate the concern of exposure to applicators.

Only workers are permitted access to the treatment areas, thus the potential for bystander exposure is expected to be negligible and therefore not of concern.

Environmental Considerations

What Happens When Saponins of *Chenopodium quinoa* Is Introduced Into the Environment?

Saponins of *Chenopodium quinoa* are expected to leach from the treated potato seed pieces into the surrounding soil. However, saponins are not persistent in the environment and will not contaminate surface water or drinking water sources.

Value Considerations

What Is the Value of Heads Up Plant Protectant?

Saponins of *Chenopodium quinoa*, the active ingredient in Heads Up Plant Protectant, suppresses rhizoctonia canker and black scurf caused by *Rhizoctonia solani* on potato.

Heads Up Plant Protectant is a soluble powder containing 63.02% of saponins of *Chenopodium quinoa* that is intended to be used as seed treatment for the suppression of rhizoctonia canker and black scurf (*Rhizoctonia solani*) on potatoes. Heads Up Plant Protectant is a non-conventional fungicide that represents an additional mode of action, and it will provide potato growers an alternative to manage rhizoctonia diseases in potato.

Measures to Minimize Risk

Labels of registered pesticide products include specific instructions for use. Directions include risk-reduction measures to protect human and environmental health. These directions must be followed by law.

The key risk-reduction measures being proposed on the label of Heads Up Plant Protectant to address the potential risks identified in this assessment are as follows.

Key Risk-Reduction Measures

Human Health

Hazard statements and symbols with appropriate precautionary measures are required to address slight inhalation toxicity. Precautionary measures are also required to address minimal irritation to the eyes and skin. Mixers, applicators and handlers must wear long-sleeved shirt and long pants, shoes, socks and waterproof gloves. Mixers must also wear a dust mask and protective eyewear.

Environment

A hazard statement is required to address toxicity of saponins to some aquatic organisms.

Other Information

The relevant test data on which the decision is based (as referenced in this document) are available for public inspection, upon application, in the PMRA's Reading Room (located in Ottawa). For more information, please contact the PMRA's Pest Management Information Service by phone (1-800-267-6315) or by e-mail (pmra infoserv(*a*)hc-sc gc ca).

Any person may file a notice of objection[5] regarding this registration decision within 60 days from the date of publication of this Registration Decision. For more information regarding the basis for objecting (which must be based on scientific grounds), please refer to the Pesticides and Pest Management portion of Health Canada's website (Request a Reconsideration of Decision) or contact the PMRA's Pest Management Information Service by phone (1-800-267-6315) or by e-mail (pmra infoserv(*a*)hc-sc gc ca).

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5 As per subsection 35(1) of the *Pest Control Products Act*.

References

A. List of Studies/Information Submitted by Registrant

1.0 Chemistry

PMRA Document Number: 1745256
Reference: 2009, DACO 2.1, 2.2, 2.12.1 and 2.14.14 for Saponins Of *Chenopodium quinoa* Technical (the active ingredient of Heads Up Plant Protectant), Data Numbering Code: 2.1, 2.2, 2.12.1, 2.14.14 Confidential Business Information

PMRA Document Number: 1745257
Reference: 2003, Product chemistry, product identity and composition, production process, and impurities, Data Numbering Code: 2.2, 2.3, 2.4, 2.5, 2.6, 2.7, 2.8, 2.9, 2.10, 2.11.1, 2.11.2, 2.11.3, 2.11.4, 2.12.1 ,2.13.2, 2.13.4, 2.14.1 Confidential Business Information

PMRA Document Number: 1745260
Reference: 2003, Preliminary analysis, certified limits and enforcement method, Data Numbering Code: 2.12.1, 2.13, 2.13.1, 2.13.3 Confidential Business Information

PMRA Document Number: 1745262
Reference: 2003, Physical and chemical characteristics, Data Numbering Code: 2.14.1, 2.14.10, 2.14.11, 2.14.12, 2.14.13, 2.14.14, 2.14.2, 2.14.3, 2.14.4, 2.14.6, 2.14.7, 2.14.9, 2.16

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2.0 Human and Animal Health

PMRA Document Number: 1745238
Reference: Oakenfull D, 1981, Saponins in food – a review, Food Chemistry 6: 19-40, Data Numbering Code: 4.8, 5.14, 6.4

PMRA Document Number: 1745239
Reference: United States Environmental Protection Agency, 2007, Biopesticides registration action document: Saponins of *Chenopodium quinoa* (PC Code 097094), Data Numbering Code: 12.5.2, 12.5.3, 12.5.4, 12.5.5, 12.5.6, 12.5.7, 12.5.8, 12.5.9

PMRA Document Number: 1745241
Reference: Francis G, Kerem Z, Makkar HPS, Becker K, 2002, The biological action of saponins in animal systems: a review, British Journal of Nutrition 88: 587-605, Data Numbering Code: 4.8, 5.14, 6.4

PMRA Document Number: 1745259
Reference: 2002, Quinoa saponins research: Results of a literature search on the structure, biological activity, toxicity and biodegradation of saponins, with particular reference to quinoa saponins, Data Numbering Code: 2.11.1, 2.16, 2.7, 3.7, 4.2.9, 4.4.1, 4.5.4, 8.2

PMRA Document Number: 1745267
Reference: 2001, Quinoa saponin toxicology report, Data Numbering Code: 4.1, 4.3.1, 4.7.1, 9.1, 9.4, 9.5.1

PMRA Document Number: 1745268
Reference: 2003, Acute oral toxicity study in rats - limit test, Data Numbering Code: 4.2.1

PMRA Document Number: 1745269
Reference: 2003, Acute dermal toxicity study in rats - limit test, Data Numbering Code: 4.2.2

PMRA Document Number: 1745270
Reference: 2003, Acute inhalation toxicity study in rats - defined LC_{50}, Data Numbering Code: 4.2.3

PMRA Document Number: 1745271
Reference: 2003, Primary eye irritation study in rabbits, Data Numbering Code: 4.2.4

PMRA Document Number: 1745273
Reference: 2003, Primary skin irritation study in rabbits, Data Numbering Code: 4.2.5

PMRA Document Number: 1745274
Reference: 2003, Dermal sensitization study in guinea pigs (Buehler method), Data Numbering Code: 4.2.6

PMRA Document Number: 1745275
Reference: Agriculture and Agri-Food Canada, 2000, Feeding strategies for minimizing nutrient excretion and odours in swine manure, Data Numbering Code: 4.3.8

PMRA Document Number: 1745277
Reference: 2004, Correspondence Document: Explainations And Waiver Requests, Data Numbering Code: 4.5, 4.5.4, 4.5.8, 9.1, 9.3.1, 9.3.2, 9.4.1, 9.4.2, 9.5.2.3, 9.6.2.3, 9.6.2.6

PMRA Document Number: 1745279
Reference: 2008, Environmental chemistry and fate of Heads Up Plant Protectant and Saponins of *Chenopodium quinoa* Technical fungicide, Data Numbering Code: 8.1

PMRA Document Number: 1745280
Reference: 2008, Metabolism and bioaccumulation of Heads Up Plant Protectant and Saponins of *Chenopodium quinoa* Technical fungicide, Data Numbering Code: 6.1, 9.5.6

PMRA Document Number: 1747708
Reference: 2009, Occupational exposure for Heads Up Plant Protection, Data Numbering Code: 5.2

PMRA Document Number: 1747709
Reference: Agriculture and Agri-Food Canada, 2005, Crop profile for potato in Canada, Data Numbering Code: 5.2, 10.2.2

3.0 Environment

PMRA Document Number: 1745239
Reference: United States Environmental Protection Agency, 2007, Biopesticides registration action document: Saponins of *Chenopodium quinoa* (PC Code 097094), Data Numbering Code: 12.5.2, 12.5.3, 12.5.4, 12.5.5, 12.5.6, 12.5.7, 12.5.8, 12.5.9

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Reference: 2008, Winter bird use of seed-rich habitats in agri-environment schemes. Agriculture, Ecosystems and Environment 126: 189–194, Data Numbering Code: 9.6.1

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PMRA Document Number: 1745278
Reference: 2008, Environmental toxicology of Heads Up Plant Protectant and Saponins of *Chenopodium quinoa* Technical fungicide, Data Numbering Code: 9.1, 9.2, 9.3.2, 9.5.2.1, 9.5.2.2, 9.5.2.3, 9.6.2.1, 9.6.2.2, 9.6.2.3, 9.6.2.4, 9.6.2.5, 9.6.2.6, 9.8

PMRA Document Number: 1745279
Reference: 2008, Environmental chemistry and fate of Heads Up Plant Protectant and Saponins of *Chenopodium quinoa* Technical fungicide, Data Numbering Code: 8.1

4.0 Value

PMRA Document Number: 1747677
Reference: 2009, Efficacy and crop tolerance of Heads Up Plant Protectant used as a potato seed piece treatment, Data Numbering Code: 10.1, 10.2.1, 10.2.2, 10.2.3, 10.3

PMRA Document Number: 1747679
Reference: 2008, Systemic acquired resistance and induced systemic resistance in plants: Literature review, Data Numbering Code: 10.2.1

PMRA Document Number: 1747709
Reference: Agriculture and Agri-Food Canada, 2005, Crop profile for potato in Canada, Data Numbering Code: 5.2, 10.2.2

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Reference: Ducheshen JM, 2005, Method for protecting plants from fungal and bacterial diseases, United States Patent Application Publication 2005/0261129 A1, Data Numbering Code: 10.2.1, 10.2.2, 10.2.3

PMRA Document Number: 1747712
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PMRA Document Number: 1747713
Reference: 2003, Potato late blight control trials, Data Numbering Code: 10.2.3

PMRA Document Number: 1747714
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PMRA Document Number: 1747715
Reference: 2005, Control of early blight, Rhizoctonia, white mold and pink rot in Russet Burbank potatoes, Data Numbering Code: 10.2.3

PMRA Document Number: 1747716
Reference: 2006, Seed treatments and seed plus foliar treatments for control of seed- and soil-borne Rhizoctonia, Data Numbering Code: 10.2.3

PMRA Document Number: 1747717
Reference: 2004, Seed treatments, in-furrow and seed plus foliar treatments for control of potato stem canker and black scurf, Data Numbering Code: 10.2.3

PMRA Document Number: 1769620
Reference: 2009, Effect of saponins of *Chenopodium quinoa* applied as seed treatment and foliarly on dry rot, common scab and black scurf diseases of potato, Data Numbering Code: M10.2.2

B. Additional Information Considered

1.0 Environment

PMRA Document Number: 1903561
Reference: Kuljanabhagavad T, Wink M, 2009, Biological activities and chemistry of saponins from *Chenopodium quinoa* Willd., Phytochem Rev 8: 473-490, Data Numbering Code: 8.1